

REMARKS/ARGUMENTS

Claims 1-6, 14-20 and 23-25 are pending in the application. Reexamination and reconsideration of the application in view of the remarks that follow are respectfully requested.

Claims 1-6, 14-20 and 23-25 were rejected under 35 U.S.C. §112 , first paragraph as not enabled. In particular, the Examiner stated: "...while being enabling for ... treatment of attachment of *S. mutants* to teeth comprising an isolated Competence Stimulating Peptide (CSP), wherein the CSP comprises SEQ ID NO:1..., [the specification] does not reasonably provide enablement for a composition or a medicament comprising an isolated Competence Stimulating Peptide (CSP) and sucrose for the prophylaxis of any condition associated with attachment of *S. mutants* to teeth or a condition which is selected from dental caries or endocarditis." This rejection is respectfully traversed.

Applicants submit that the specification fully satisfies the requirement for enablement under 35 U.S.C. § 112, first paragraph, with respect to all pending claims. "The law does not require a specification to be a blueprint in order to satisfy the enablement requirement," *Staehlin v. Secher*, 24 U.S.P.Q. 2d 11513, 1516 (Bd. Pat. App. & Int. 1992). Even in the relatively "unpredictable" arts, one need not necessarily disclose how to make each and every embodiment encompassed by the claim. For example, in *In re Angstadt*, 537 F.2d 498, 190 U.S.P.Q. 214 (C.C.P.A. 1976), the court noted that some experimentation is often to be expected in unpredictable areas of technologies. The court further observed that if § 112 required a disclosure of a test with every species covered by a claim in an unpredictable art, then a prohibited number of actual experiments would have to be performed, discouraging the filing of patent applications in unpredictable areas. *Id.*

Claims 1-6 and 25 are directed to compositions comprising an isolated CSP and sucrose, wherein the CSP comprises SEQ ID NO:1 and wherein the composition is capable of preventing attachment of *S. mutans* to teeth. Claims 14-20 are directed to a medicament for the treatment or prophylaxis of a condition associated with the attachment of *S. mutans* to teeth, comprising an isolated CSP in an amount effective to reduce the attachment of *S. mutans* to teeth, wherein the CSP comprises SEQ ID NO:1. Claim 23 is directed to a composition comprising an isolated CSP and sucrose, wherein the CSP consists of SEQ ID NO:1. Claim 24 is directed to a medicament for the treatment or prophylaxis of a condition associated with the attachment of *S. mutans* to teeth, comprising an isolated CSP in an amount effective to reduce the attachment of *S. mutans* to teeth, wherein the CSP consists of SEQ ID NO:1.

Instant specification teaches using compositions containing CSP with or without sucrose for the prevention or prophylaxis of oral diseases and endocarditis (pages 6, 9-10). It is a discovery of the inventors that while sucrose alone stimulates attachment of *S. mutans* to teeth, a combination of sucrose with CSP inhibits such attachment (pages 6 and 11). While not wanting to be bound by a theory, inventors believe that sucrose enhances the ability of glucosyltransferase-dependent non-pathogenic bacteria to adhere to teeth creating a barrier for subsequent *S. mutans* attachment (pages 6 and 11).

The presence of attached *S. mutans* directly correlates with the incidence of caries. As demonstrated by Seki *et al.* (*Evaluation Of Mutans Streptococci In Plaque And Saliva: Correlation With Caries Development In Preschool Children*, Journal of Dentistry, (2003) 31:283-290; Attachment A), 80% of subjects with high count of attached *S. mutans* had caries, as compared to only 14% of the subjects with high saliva counts of *S. mutans* having caries. Accordingly, those skilled in the art would

recognize that inhibition of *S. mutans*' attachment achieved by the present invention prevents caries.

With respect to infectious endocarditis, the disease has been long linked to *S. mutans* attached to decaying teeth (Schelenz *et al.*, *S. Mutans Endocarditis: Beware Of The Diptheroid*, Journal of the Royal Society of Medicine, 2005; 98: 420-421; Attachment B; Lowry *et al.*, *Hearts and Mouths: Perceptions of Oral Hygiene by at-Risk Heart Surgery Patients*, British Dental Journal, 2005; 199: 449-451; Attachment C). Accordingly, a composition that removes the cause of endocarditis, *S. mutans*, from the mouth effectively prevents endocarditis.

Furthermore, the specification demonstrates that glucosyltransferases and their substrate (sucrose) are required for the *S. mutans* attachment to a smooth surface (Examples 1 and 2, page 15). The specification also demonstrates that glucosyltransferases are dramatically inhibited by CSP (see Figure 4 that shows reduction in glucosyltransferase expression in wild-type *S. mutans*, but not in the strain deficient in CSP (comC strain) and Figure 7 where addition of CSP reduces the glucosyltransferase expression 100 fold). It is recognized that without active glucosyltransferases no attachment of *S. mutans* takes place (Tsumori *et al.*, *The Role Of The Streptococcus Mutans Glucosyltransferases In The Sucrose-Dependent Attachment To Smooth Surfaces: Essential Role Of The Gtfc Enzyme*, Oral Microbiology and Immunology, 1997 12: 274-280; Attachment D).¹ Accordingly, experiments showing inactivation of glucosyltransferases by CSP indicate that CSP is likely to inhibit the attachment of *S. mutants* to teeth (Examples 1-6, pages 15-17).

¹ Tsumori states: "Previous results have indicated that the glucosyltransferase activities of mutans streptococci are required for sucrose-dependent colonization of tooth surfaces". (emphasis added)

The inventors further confirmed ability of CSP in a combination with sucrose to inhibit attachment of *S. mutants* to teeth (page 17). Inventors conducted an *in vitro* assay using a plastic Petri dish as a suitable model for a smooth tooth surface. In the past, attachment of *S. mutans* to glass has been used as a simulation of the growth of plaque on a tooth surface (assay developed by Dr. Howard Kuramitsu referenced in Tsumori; Attachment D). Polystyrene has been shown to have cell adhesion properties similar to that of glass (A.Yamamoto et al., Quantitative Evaluation of Cell Attachment to Glass, Polystyrene, and Fibronectin- or Collagen-Coated Polystyrene by Measurement of Cell Adhesive Shear Force and Cell Detachment Energy, *Cell Detachment Energy to ECM*, 1999, 114-124; Attachment E). Therefore, one of skill in the art would immediately recognize that *S. mutans* that fail to adhere to plastic (polystyrene) Petri Dish, will also fail to adhere to glass and surface of teeth.

In addition to these general teachings, the specification provides specific examples of compositions of the present invention. The specification describes one embodiment, in which 0.05 -30% (w/w) of CSP is used in the composition (page 6). Additionally, specification provides seven specific examples of mouth wash, dentifrice gel, chewing gum, soft drink, and candy formulations containing CSP with or without sucrose (pages 19-22). Other ingredients that may be added to the compositions of the present invention are also provided in the specification (pages 7-10). An exemplary procedure for preparing a formulation comprising CSP is also described (pages 18-19). Furthermore, the specification provides an example of a treatment regimen where the composition of the present invention is applied to the oral cavity of the subject soon after the subject eats a food containing sucrose, from one to three times daily (pages 10-11).

Therefore, a reasonable amount of general guidance and a sufficient number of specific examples are given by the specification with respect to the claimed

compositions and medicaments. Therefore, a merely routine experimentation would be required to adjust therapeutically effective amount of CSP depending on the condition to be treated, its severity, the treatment regimen to be employed, the pharmacokinetics of the agent used, as well as the patient (animal or human) treated (page 10). Accordingly, one skilled in the art would be able to practice any of the instantly claimed embodiments without undue experimentation in light of the teachings of the instant specification.

The Examiner presents a number of arguments in support of the rejection. Applicants briefly address these arguments in the order they appear in the Office Action.

(1) References Cited for Teaching of Sucrose-Dependent Adherence of *S. Mutants* to Teeth

On pages 3-4 of the Office Action, the Examiner describes a number of references that teach sucrose-dependent adherence of *S. mutants* to teeth and sucrose-mediated caries. The Examiner then concludes that the art provides "specific examples why one would not want to use sucrose for the inhibition of *S. mutants* to teeth." (p.7) Such teaching away from the claimed invention, however, is irrelevant to the enablement inquiry. In fact, to view enablement requirement otherwise would make patenting non-obvious and novel inventions impossible. *Gould v. Quigg*, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987) ("The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it.") Moreover, it is not even required that the inventors "comprehend the scientific principles on which the practical effectiveness of the invention rests." *Fromson v. Advance Offset Plate, Inc.* 720 F.2d 1565, 1570 (Fed. Cir. 1983).

As discussed above, the discovery that a mixture of CSP and sucrose inhibits attachment of *S. mutants* to teeth is in the very heart of the present invention. The importance of this discovery cannot be overlooked. Although the negatives effects of sucrose found in food products is well-recognized, the public is reluctant to adhere to any diet modification. Moreover, sucrose is naturally present in many fruits and juices. Therefore eliminating or reducing the added sugar from one's diet does not entirely solve the problem. The present invention does not require any diet modification. Instead, the claimed composition takes advantage of the essential role sucrose plays in the life cycle of *S. mutans*. When sucrose alone is added, *S. mutans* uses it for attachment. When sucrose is added together with CSP, the commensal bacteria are stimulated and *S. mutans* are displaced from the micorflora.

(2) Reference Cited for Teaching of Use of Antibiotics in Prophylaxis and Treatment of Endocarditis

On pages 4-5 of the Office Action, the Examiner describes a number of references that teach antibiotic treatment and proprphylaxis of endocarditis. Again, such teaching of alternative methods of treatment does not make the instant claims to compositions inhibiting attachment of *S. mutans* to teeth not enabled. As discussed above, infectious endocarditis results when *S. mutans* from the decayed teeth penetrate the blood vessels and invade the heart valves. (Schelenz; Attachment B). Poor dental hygiene is linked to the heart infection especially in susceptible people (Lowry; Attachment C). Accordingly, a composition that inhibits attachment of *S. mutans* to teeth and, thus, prevents their accumulation in the oral cavity, will prevent endocarditis.

The advantages of using compositions of the present invention for treatment of endocarditis over existing methods may be illustrated by reference to a report by Prabhu *et al.* (*Antimicrobial Susceptibility Patterns among Viridans Group*

Streptococcal Isolates from Infective Endocarditis Patients from 1971 to 1986 and 1994 to 2002, Antimicrobial Agents and Chemotherapy, 2004; 48: 4463-4465; Attachment F). This report indicates that emerging antibiotic resistance is a major problem in treatment and prophylaxis of infective endocarditis caused by viridans streptococci (a group that includes *S. mutans*). Resistance to nearly every antibiotic was found (penicillin, erythromycin, clindamycin). En route to full-blown resistance, antibiotics become progressively less effective and require a larger dose (ciprofloxacin and derivatives). In contrast, CSP is an endogenous *S. mutans* compound and the development of resistance to CSP is unlikely.

(3) No “Evidence That Claimed Composition is Capable of Inducing Protective Immunity”

The Examiner appears to believe that in order to claim prophylaxis of a condition associated with attachment of *S. mutans*, applicants are required to demonstrate that the compositions of the present invention are able to induce protective immunity (page 5 of the Office Action). Applicants respectfully disagree.

Applicants do not claim use of CSP-sucrose compositions to induce an immune response. Instead, the attachment of *S. mutans* to teeth is prevented so that no infection is established in the first place. The prophylaxis is achieved by constant application, e.g. via mouthwash or a dentifrice, not by the generation of antibodies, as it would be required with an immunological composition. Therefore, a demonstration of immunological activity of the compositions of the present invention is not required in order to claim prophylaxis of a condition associated with attachment of *S. mutans*

(4) No Examples Showing That Sucrose Had A “Role In Inhibiting Attachment ... Or ... Actually Prevented Any Condition Associated With Attachment Of *S. Mutans* To Teeth”

The Examiner notes that administration of CSP and sucrose are exemplified in the specification. Office Action, page 6. (“In fact Example 7 only exhibits a composition with CSP and sucrose present.”) Examiner appears to believe, however, that instant claims are not enabled because (a) there are no examples demonstrating role of sucrose in inhibiting the attachment; (b) the “examples do not display a form of prevention;” and (c) “[t]here are no instances where an anti-caries agent was present in the composition thereby helping with the prevention of *S. mutans* attachment, dental caries or endocarditis.” Applicants disagree.

First of all, “[c]ompliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed.” MPEP, §2164.02. Moreover, “[a]n applicant need not have actually reduced the invention to practice prior to filing.” *Id.* The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).

As discussed above, the specification fully describes claimed compositions and medicaments. Furthermore, contrary to the Examiner’s belief, instant specification does provide examples that demonstrate role of sucrose in inhibiting attachment of *S. mutans*, which is promoting growth of competing non-pathogenic bacteria. For example, Example 7 on page 17 describes *in vitro* assay that was performed to determine whether CSP can inhibit the attachment of *S. mutans* to a smooth surface in a presence of sucrose. As demonstrated in Figure 8, when sucrose was added to the medium, the wild-type *S. mutans* readily attached to the surface of a

Petri dish. However, when bacteria were challenged with CSP added to the sucrose-containing medium 8µg/l, less than 8% of *S. mutans* attached.

This example therefore demonstrates that CSP can inhibit the attachment of *S. mutans* to a smooth surface even when sucrose is present. As explained in the specification, since other early colonizing oral bacteria rely on their own *gtf* genes for efficient adherence and are not affected by the presence of CSP, such non-pathogenic bacteria will gain a competitive advantage over *S. mutans* in the presence of sucrose, which is a substrate for glucosyltransferase. (page 6). Therefore, sucrose stimulates growth of non-pathogenic bacteria competing with *S. mutans*, while CSP selectively inhibits *gtf* genes of *S. mutans*, which impairs their ability to metabolize sucrose and attach to the surface.

With respect to the examples demonstrating prevention, it is applicants belief that such examples are not required in order to satisfy enablement requirement. As discussed above, the presence of attached *S. mutans* directly correlates with the incidence of caries. Accordingly, those skilled in the art would recognize that inhibition of *S. mutans*' attachment achieved by the present invention prevents caries. Similarly, infectious endocarditis has been long linked to *S. mutans* attached to decaying teeth (Schelenz; Attachment C). Accordingly, a composition that removes *S. mutans* from the mouth effectively prevents endocarditis.

Finally, since the present invention does not rely on traditional anti-caries agents to prevent caries, such agents are optional in the present invention. Accordingly, the enablement requirement is satisfied without examples utilizing compositions containing such optional ingredients.

(5) "The Quantity of the Experimentation Necessary Would Be Undue for the Utilization of Any Amount of CSP"

The Examiner also states that "[t]he specification lacks guidance with respect to the utilization of CSP" and that the "[q]uantity of experimentation necessary would be undue for the utilization of any amount of CSP." Office Action, page 6. Applicants respectfully disagree.

As discussed in more detail above, instant specification provides seven specific examples of mouth wash, dentifrice gel, chewing gum, soft drink, and candy formulations containing CSP with or without sucrose (pages 19-22). Other ingredients that may be added to the compositions of the present invention are also provided in the specification (pages 7-10). An exemplary procedure for preparing a formulation comprising CSP is also described (pages 18-19). Furthermore, the specification provides an example of a treatment regimen where the composition of the present invention is applied to the oral cavity of the subject soon after the subject eats a food containing sucrose, from one to three times daily (pages 10-11).

Therefore, a reasonable amount of general guidance and a sufficient number of specific examples are given by the specification with respect to the claimed compositions and medicaments. Therefore, a merely routine experimentation would be required to adjust therapeutically effective amount of CSP depending on the condition to be treated, its severity, the treatment regimen to be employed, the pharmacokinetics of the agent used, as well as the patient (animal or human) treated (page 10). Accordingly, one skilled in the art would be able to practice any of the instantly claimed embodiments without undue experimentation in light of the teachings of the instant specification.

(6) “The Results of the Putative Treatment Regimens Exemplified in the Examples Are Unclear”

As noted above, the law of enablement does not require actual examples to be disclosed. MPEP, §2164.02 (“[a]n applicant need not have actually reduced the invention to practice prior to filing.”) “An example may be ‘working’ or ‘prophetic.’ A working example is based on work actually performed. A prophetic example describes an embodiment of the invention *based on predicted results* rather than work actually conducted or results actually achieved.” *Id.* (emphasis added) Therefore, it is improper for the Examiner to request results of putative examples.

(7) “There Was No Material Similar to Tooth Enamel”

The Examiner appears to think that Petri Dish is not a proper model for tooth enamel (page 6). However, as discussed above, in the past, attachment of *S. mutans* to glass has been used as a simulation of the growth of plaque on a tooth surface (assay developed by Dr. Howard Kuramitsu referenced in Tsumori; Attachment D). Polystyrene that is typically used to manufacture Petri Dishes has been shown to have cell adhesion properties similar to that of glass (Yamamoto et al., Attachment E). Therefore, one of skill in the art would immediately recognize that *S. mutans* that fail to adhere to plastic (polystyrene) Petri Dish, will also fail to adhere to glass and surface of teeth.

Furthermore, an inactivation of glucosyltransferase enzymes is generally known to prevent any attachment of *S. mutans* to tooth surface (see Attachment D). The inventors have confirmed that the adherence of *S. mutans* is effectuated by the enzymes glucosyltransferases. Without these enzymes no attachment takes place (Fig. 2). Therefore, experiments showing inactivation of glucosyltransferase *in vitro* are well-known to reliably predict that *S. mutans* will not attach to teeth.

The inventors have shown that glucosyltransferase is dramatically inhibited by CSP. The reduction in glucosyltransferase expression shown in Fig. 4 is due to CSP, since no reduction is seen in the strain deficient in CSP (comC strain). Similarly, experimental addition of CSP reduces the glucosyltransferase expression 100 fold (Fig. 7). Based on these results, one skilled in the art would have concluded that CSP inhibits attachment of *S. mutans* to teeth.

(8) Information About What Non-Pathogenic Organisms Will or Will Not Adhere to the Teeth

The applicants are not required to know how their invention works in order to satisfy the enablement requirement. *Fromson v. Advance Offset Plate, Inc.*, 720 F. 2d 1565, 1570 (Fed. Cir. 1983) (Inventor “need not comprehend the scientific principles on which the practical effectiveness of his invention rests.”) Thus, applicants are not required to study what non-pathogenic organisms will or will not adhere to the teeth in order to satisfy the enablement requirement with respect to the claimed compositions and medicaments.

(9) “Without Any Specific Guidance To The Contrary, [the Invention] Could Result in Damage To The Patient”

The enablement requirement does not place a duty on the applicants to demonstrate that the claimed compositions comprising CPA with or without sucrose are completely safe, effective, and reliable. *In re Kimmel*, 292 F.2d 948, 954 (C.C.P.A. 1961). (“There is nothing in the patent statute ... that gives the Patent Office the right or the duty to require an applicant to prove that compounds or other materials which he is claiming , and which he has stated are useful for ‘pharmaceutical application,’ are safe, effective, and reliable for use with humans.”)

In view of the foregoing, it is respectfully submitted that claims 1-6, 14-20, and 23-25 are enabled by the specification in their full scope and that the rejection under 35 U.S.C. § 112, first paragraph, should be withdrawn.

Claims 2, 3, 6, 15, 17 and 20 were rejected under 35 U.S.C. § 112, second paragraph, as not clear. In particular, the Examiner is unclear what are the recited anti-caries agent, histidine rich polypeptides, and non-immunogenic acid segments of proline-rich proteins. This rejection is respectfully traversed.

It is respectfully submitted that the objected terms are widely used and well-known in the art (see for example, U.S. Patent Nos. 4,725,576; 5,912,230; 5,885,965; 5,631,228; 5,646,119; 5,013,542; and 5,486,503). Furthermore, the specification itself clearly defines these terms on pages 7-8 of the specification. With respect to the optional anti-caries agents, the specification describes not one, but nine groups of suitable compounds (see the text from pages 7-8 of the specification reproduced below). With respect to histidine rich polypeptides, the specification incorporates by reference six patents that provide a detailed description of such compounds (see section 3) in the text reproduced below). With respect to non-immunogenic acid segments of proline-rich proteins, the specification incorporates by reference U.S. Patent No. 5,013,542 that provides a detailed description of such compounds (see section 7) in the text reproduced below). For the Examiner's reference, applicants reproduced relevant section of the specification below:

The composition of this invention can further include one or more an **anti-caries agents** in addition to CSP. It is contemplated that various **anti-caries reagents well known in the art** can be included in the compositions and medicaments of the present invention and include, but are not limited to:

(1) substantially water insoluble noncationic antimicrobial agent, including but not limited to, Xylitol, triclosan, halogenated diphenyl

ethers, benzoic esters; sesquiterpene alcohols (e.g., farnesol, nerolidol, bisabolol, and santalol), halogenated carbanilides, phenolic compounds including phenol and its homologs, mono-, poly-alkyl and aromatic halophenols, resorcinols (e.g., hexyl resorcinol), catechols (e.g., 2,2'-methylene bis (4-chloro-6-bromophenol), and bisphenolic compounds;

(2) non-steroidal anti-inflammatory drugs (NSAIDs), which can be characterized into five groups: (1) propionic acids (e.g., ibuprofen, indoprofen, ketoprofen, naproxen, benoxaprofen, flurbiprofen, fenoprofen, fenbufen, piroprofen, carprofen, oxaprozin, pranoprofen, miroprofen, tioxaprofen, suprofen, alminoprofen, tiaprofen, fluprofen, and bucloxic acid); (2) acetic acids (e.g., ketorolac, indomethacin, sulindac, tolmetin, zomepirac, diclofenac, fenclofenac, alclofenac, ibufenac, isoxepac, furofenac, tiopinac, zidometacin, acetaminophen, fentiazac, clidanac, oxpinac, and fenclozic acid); (3) fenamic acids (e.g., mefenamic acid, meclofenamic acid, flufenamic acid, niflumic acid, and tolfenamic acid); (4) biphenylcarboxylic acids (e.g., diflunisal and flufenisal); and (5) oxicams (e.g., piroxicam, sudoxicam and isoxicam);

(3) **histidine-rich polypeptides** ("HRPs," also referred to as histatins), such as histatin-based peptides disclosed in U.S. Patent Nos. 4,725,576; 5,912,230; 5,885,965; 5,631,228; 5,646,119; and 5,486,503, each of which is incorporated herein by reference;

(4) fluorides reagents including sodium fluoride, stannous fluoride, amine fluorides, and monosodiumfluorophosphate;

(5) casein;

(6) plaque buffers such as urea, calcium lactate, calcium glycerophosphate, and strontium polyacrylates;

(7) **non-immunogenic amino acid segments of proline-rich proteins that inhibit the adhesion of disease-causing microorganisms to tooth surfaces**, as described in U.S. Patent No. 5,013,542, incorporated herein by reference. The active ingredient can be derived from segmenting a natural or synthetic, proline-rich protein, to

provide a non-immunogenic ingredient. The non-immunogenic amino acid segment can be obtained by various techniques, such as by cloning, or by synthesizing analogs of the natural molecules or their segments by chemical means. The non-immunogenic amino acid segment can also be obtained enzymatically or by cleaving the proline-rich protein derived from human saliva by the enzyme trypsin;

(8) antibodies of *S. mutans*, including intact molecules as well as functional fragments thereof, such as monoclonal IgG antibodies that specifically bind an antigen on the surface of *S. mutans*, including the following antibodies disclosed in U.S. Patent No. 6,231,857, incorporated herein by reference: the hybridoma deposited with the American Type Culture Collection as ATCC No. HB12559 (designated SWLA1), the hybridoma deposited with the American Type Culture Collection as ATCC No. HB 12560, (designated SWLA2), and the hybridoma deposited with the American Type Culture Collection as ATCC No. HB 12258 (designated SWLA3). and

(9) other pharmaceutically acceptable vehicles, diluents and additives such as antioxidants, buffers, bactericidal antibiotics and solutes which render the formulation isotonic in the intended recipient; and aqueous and non-aqueous sterile suspensions which may include suspending agents and thickening agents.

Therefore, applicants submit that terms "anti-caries agent," "histidine rich polypeptides," and "non-immunogenic acid segments of proline-rich proteins" of claims 2, 3, 6, 15, 17 and 20 will be readily understood by those skilled in the art. Accordingly, the rejection of claims 2, 3, 6, 15, 17 and 20 under 35 U.S.C. § 112 should be withdrawn.

Appl. No. 10/614,072
Amdt. Dated December 23, 2005
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In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.


If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los Angeles, California telephone number (213) 337-6700 to discuss the steps necessary for placing the application in condition for allowance.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1314.

Respectfully submitted,
HOGAN & HARTSON L.L.P.

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By: _____


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